

OCT -8 1996

UNITED STATES SURGICAL CORPORATION
510(K) PREMARKET NOTIFICATION
USSC* POLYSORB* CSL** SUTURE

K963253

**510(k) SUMMARY OF INFORMATION SUPPORTING
SAFETY AND EFFECTIVENESS:**

As is evident in the submitted information on function, indications and materials, USSC* POLYSORB* CSL** sutures are substantially equivalent to the currently marketed USSC* POLYSORB* suture as summarized below:

- USSC* POLYSORB* CSL** sutures and the existing USSC* POLYSORB* sutures are composed of biosafe materials.
- USSC* POLYSORB* CSL** sutures and the existing USSC* POLYSORB* sutures are indicated for use in general soft tissue approximation and/ or ligation and ophthalmic surgery but not use in cardiovascular or neural tissue.
- USSC* POLYSORB* CSL** sutures and the existing USSC* POLYSORB* sutures are manufactured in the same facilities using similar processes and controls.
- USSC* POLYSORB* CSL** sutures and the existing USSC* POLYSORB* sutures are packaged in the same facilities using similar materials, processes and controls.
- USSC* POLYSORB* CSL** sutures and other products currently marketed by United States Surgical Corporation are sterilized in the same facilities using similar processes and controls.